**REMARKS**

The Office Action mailed November 10, 2005 (henceforth referred to as the "Office Action") rejected claim 43 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention.

Applicant filed a Response and Amendment After Final on April 10, 2006 following a telephonic interview with the Examiner. Applicant thereafter received an Advisory Action mailed April 26, 2006, which indicated that the above Amendments did not place the application in condition for allowance and that the requested claim amendments would not be entered. Applicant thereafter again spoke with the Examiner over the telephone and agreed to file a RCE along with the present Response and Amendment to give the Examiner sufficient time to reconsider the rejections in light of the present claim amendments.

With regard to the prior art, the Office Action rejected claims 23-25, 32, 35, and 44 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,007,903 to Ellard (henceforth, "Ellard"). The Office Action also rejected claims 23, 26, and 33-34 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,836,921 to Mahurkar (henceforth, "Mahurkar"). Further, claims 37-42 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 3,636,940 to Gravlee (henceforth, "Gravlee"). Additionally, claims 27-28 and 31 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Ellard in view of U.S. Patent No. 5,494,044 to Sundberg (henceforth, "Sundberg"). Finally, claims 29, 30, and 36 were independently rejected by the Office Action under 35 U.S.C. § 103(a) as allegedly being unpatentable over Ellard and Sundberg in further view of U.S. Patent No. 4,265,249 to Schindler et al. (henceforth, "Shindler"), U.S. Patent No. 5,238,003 to Baidwan et al. (henceforth, "Baidwan"), and U.S. Patent No. 5,738,109 to Parasher (henceforth, "Parasher"), respectively.

Notably, no prior art rejections are contained in the Office Action against claim 43. Applicant herein has addressed the allowability of claim 43, and independent method claim, against the prior art cited against other method claims (namely, Gravlee).

In the present Response and Amendment, claims 23, 34, 37, and 42-43 have been

amended. These amendments to the claims have been introduced to correct typographical errors, to address formality issues raised by the Office Action, and to otherwise refine the claims to place the present application in better condition for allowance and/or appeal.

No new matter has been introduced by any of these amendments. Reconsideration in view of the above amendments and following remarks is respectfully requested.

## Claim Rejections

Each of the grounds for claim rejections are addressed below.

### 35 U.S.C. § 112, second paragraph

Claim 43 was rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. Applicant has by the amendments above corrected this claim in a manner that obviates all rejections under section 112. Reconsideration of these claims and removal of the rejections based upon section 112 are thus respectfully requested.

### 35 U.S.C. §§ 102(b) and 103(a) - Ellard and Mahurkar

All claims stand rejected based upon the prior art for the reasons outlined above. Insofar as this ground for rejection applies to the claims as originally presented and as currently amended, Applicant respectfully traverses.

Applicant's prior Amendment dated August 31, 2005 made several arguments that were deemed unpersuasive by the Office Action. Applicant noted that Applicant's claims as previously presented were allowable over both Ellard and Mahurkar because those references failed to disclose a device that comprises "a flexible, hollow, and elongate catheter" as was recited in all pending claims. Rather, these two prior art references taught devices having retractable hollow needles that, in Applicant's opinion, are not flexible catheters as required by the claims. In particular, the remarks contained in that prior Amendment stated:

> The difference between the flexible, hollow, elongate catheter as called for in claim 23 and the hollow need disclosed by

> Ellard and Mahurkar is very significant. The fact that the catheter of the device of the present invention is flexible and elongate is important in that it enables the catheter to follow the internal conformation of an internal cavity of a mammal when the device is used for collection of a fluid sample from such an internal cavity for example, where a fluid sample is to be collected from the uterus of a human female the catheter must follow a curved path as it extends into the cavity. Accordingly, it is absolutely important and essential that the catheter be flexible. In addition, it is equally important the catheter is not a rigid device such as a hollow needle since a hollow needle or a similar device would be likely to puncture the wall of the uterus or other internal cavity (particularly if the rigid device was also sharp as in a needle).

In response to these remarks, the Office Action reasserted its position in rejecting the claims based on the premise that the term "flexible" as used in Applicant's claims could be construed broadly to embrace a needle. In particular, the Office Action noted:

> "The Examiner notes that the claim language only requires a flexible, hollow, elongate catheter. In response to applicant's argument that the references fail to show certain features of Applicant's invention, it is noted that the features upon which Applicant relies (i.e. that the flexible, hollow, catheter be capable of following the internal conformation of an internal cavity of a mammal) are not recited in the rejected claim(s). … Examiner notes that none of [the dictionary] definitions require the term 'flexible' to mean capable of tracking a curved path or conformation."

While Applicant disagrees with the Office Action's conclusion that the terms "flexible" and "catheter" as recited in all of Applicant's claims, when read together by one skilled in the relevant art, would not distinguish over a metal needle, Applicant has herein amended

independent claim 23, the lone apparatus claim present in the application in independent format, to explicitly recite an appropriate definition of flexible as clearly supported by Applicant's specification. In particular, claim 23 now recites "said catheter being sufficiently flexible so as to be adapted to bend and follow the conformation of an internal cavity upon encountering walls of said cavity during insertion into said cavity without damaging tissue of said cavity."

As noted previously, the "flexible, hollow, elongate catheter" present in the apparatuses according to the present invention are adapted for use in collecting fluid samples from soft internal cavities of a mammal, such as a uterus. As will be readily appreciated by one skilled in the art, a needle is clearly not suitable for this purpose regardless of whether that needle can or cannot be flexed or bent slightly when axial forces are applied. Such needles are neither designed for nor suitable for insertion into a tissue cavity to collect fluid as they are not capable of bending and following the walls of the cavity during insertion without damaging tissue.

Applicant's specification makes clear that its catheter is designed to perform in this fashion. This feature is explicitly described in Applicant's specification, for example, within Example 1 which begins at page 10, line 12. This example explains that the exemplary catheter has a fully extended length of about 7cm, and that "[i]f the uterine cavity is shorter than this then the flexible catheter will bend and so not damage the lining." Clearly, if the devices of Ellard or Mahurkar were used in this fashion, the needle would puncture or scrape the uterine lining, not only harming the patient but also potentially contaminating the fluid sample being collected.

The language presently added to claim 23 therefore explicitly defines the qualities that the flexible, hollow, elongate catheter has. Clearly, these qualities are not possessed by the devices described in Ellard or Mahurkar as Applicant is aware of no known needle that has such characteristics. The Ellard and Mahurkar devices are not intended for use in procedures for collecting fluid samples from internal cavities - modifications to those devices to produce new devices having the qualities recited by Applicant's claim 23 would not be obvious one skilled in the art. Such modifications are not in any way suggested by the prior art references of record, including Sundberg, Schindler, Baidwan and Parasher, and the Office Action provides no rationale for such modifications.

In this regard, the retractable needles as disclosed in Ellard and Mahurkar are not a

"flexible, hollow, elongate catheter" as that element is defined in Applicant's claims 23-36 and 44, and the prior art provides no teaching or suggestion to modify those retractable needles to produce applicant's claimed fluid collection device. Reconsideration of claims 23-36 and 44 and a notice of allowability is respectfully requested.

35 U.S.C. § 102(b) - Gravlee

Claims 37-43 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Gravlee. Insofar as this rejection applies to these claims as presently amended, Applicant respectfully traverses as follows.

With regard to the rejections of independent method claims 37 and 43 based upon the Gravlee reference, it is Applicant's belief that the Examiner has misunderstood how the limitations of those claims distinguish over the prior art. Despite the Office Action's assertion to the contrary, the bare contention that Gravlee's device could somehow comprise a "flexible, hollow, elongate catheter" does not make it so. Without basis, the Office Action assumes improperly that all plastics are flexible, which is a complete fallacy, and presumes that the "tubes 21 and 22" disclosed in Gravlee therefore would be flexible. Notably, Gravlee at col. 1, lines 69-75, discusses the problem of devices sometimes being too long for safe insertion into the uterus, how such problem can pierce or damage the uterine wall, and how it would be advantageous if a device that can be regulated to control the maximum distance it will extend into the uterus. Later, Gravlee describes its device at col. 4, lines 49-72, as controlling the maximum insertion distance by adjusting the "sealing member 23". One skilled in the art would not conclude that Gravlee's tubes 21 and 22 are flexible from this disclosure, but rather the exact opposite. There would hardly be a need for an adjustable sealing member 23 if the tubes 21 and 22 were sufficiently flexible such that they were incapable of piercing or otherwise damaging the uterine wall.

As such, Applicant respectfully submits that Gravlee fails to anticipate or render obvious the present invention because it fails to teach or suggest the use of a flexible, hollow, elongate catheter as recited in independent claims 37 and 43.

Second, even if Gravlee disclosed a flexible catheter as claimed by Applicant, it still does

not disclose (specifically with respect to claim 37) the method steps of:

> 1) penetrating into the internal cavity by moving the catheter into the cavity while simultaneously passing wash fluid through the hollow catheter to wash at least a portion of the surface of the internal cavity during said penetrating; and
>
> 2) subsequently (i.e., after the penetrating step) retracting the catheter from the cavity while simultaneously collecting a fluid sample by aspirating the wash fluid through the hollow catheter during said retracting.

Independent method claim 37 has two separate and sequential method steps, with the sequential nature being indicated by the use of the language "subsequently" in the claim. This aspect of the invention as recited in claim 37 is important as it permits a good wash of the length of the cavity while also allowing for improved aspiration of fluid sample from the cavity. According to Applicant's claims, the catheter penetrates the cavity and simultaneously emits wash fluid as the catheter penetrates into the cavity. The second, subsequent step as recited in claim 37 describes retracting the catheter from the cavity and simultaneously aspirating wash fluid as the catheter retracts from the cavity.

As noted during the telephonic interview with the Examiner, the Office Action apparently has confused Applicant's prior remarks with regard to the previously pending claims to somehow be alleging that Gravlee doesn't disclose the simultaneous washing and aspirating of fluid. Clearly, this is not what the Applicant has claimed nor what Applicant has described in prior remarks.

To clarify, the device described in Gravlee uses two hollow tubes 21 and 22 because its mechanism of operation requires that wash fluid be expelled through one tube into the cavity while the second tube at the same time (not "subsequently") aspirates the wash fluid from the cavity. This two-tube design described in Gravlee is essential to its operation because the Gravlee device operates on a theory of "negative pressure" (i.e., a vacuum or suction) within the uterus. See Gravlee at col. 3, lines 18-30. In the Gravlee device, when the plunger of the syringe is moved backwards a sucking force is transmitted through the a first one of the tubes to produce

a vacuum inside the uterine cavity. This vacuum draws fluid into the uterine cavity through the second tube (from a reservoir of fluid), and this fluid is at the same time aspirated into the fluid inlet tube due to the same sucking force. Logically, this mechanism is quite different from the device of the present invention, and exemplifies that Gravlee therefore does not teach the methods claimed by Applicant in claims 37-42.

The Applicant has described and claimed two sequential steps regarding the penetration and retraction of the catheter into/from the cavity that are performed in succession. The catheter penetration step is synchronized with simultaneous emitting of wash fluid, while the subsequent catheter retraction step is synchronized with simultaneous aspirating of the previously emitted wash fluid. As Gravlee's device operates on a completely different theory than Applicant's device, the use of the Gravlee device does not cause one to practice the steps of Applicant's method claims. Gravlee does not teach the emitting of wash fluid while its tubes are penetrating into the cavity. Further, Gravlee does not teach the aspirating of wash fluid from the cavity while its tubes are retracting from the cavity. Neither of these two steps are disclosed, taught, or otherwise suggested by Gravlee or any of the other prior art references made of record. The presence of both of these two separate steps in Applicant's claims 37-42 therefore render Applicant's claimed invention novel and non-obvious.

Likewise, independent method claim 43 (which was not rejected based upon prior art) contains similar limitations that render it patentable over the prior art. First, like claim 37, it recites the presence of a "flexible, hollow, elongate catheter," which is not supported by the disclosure of Gravlee. Second, again like claim 37, it recites two separate and sequential method steps (steps 'iii' and 'iv' indicated in the claim), with their sequential nature being indicated by the use of the language "subsequently" in that claim. The first step describes moving a plunger to cause a catheter to penetrate the cavity while simultaneously emitting wash fluid. The second, subsequent, step describes moving the plunger to cause the catheter to retract from the cavity while simultaneously aspirating the wash fluid. Neither of these two steps are disclosed, taught, or otherwise suggested by Gravlee or any of the other prior art references made of record.

Furthermore, Applicant notes that Gravlee does not teach or suggest a plunger whose movement causes a catheter to penetrate or retract from a cavity (which is recited in claim 43 but

not equivalently present in claim 37). Additionally, other structural limitations recited in step 'i' of claim 43, including a barrel and plunger defining a fluid chamber, and a catheter being in operative engagement with the plunger, are not present in Gravlee.

Thus, claim 43 all currently pending claims are presently allowable over the prior art of record.

## Conclusion

In view of the foregoing, the Applicant respectfully requests that the Examiner consider the claims as amended for examination on the merits. A timely allowance of the pending claims is requested.

Applicant has transmitted this Response and Amendment concurrently with a Request for Continued Examination and a transmittal document serving as a Petition for Extension of Time for three months, and a check for the amount of the fee believed due in conjunction with that that Petition (third month fee minus the previously paid second month fee, taking into account small entity status). If the appropriate fee amount has not been identified and specifically submitted with the Petition for Extension of Time, please charge any additional fees or credit any overpayments to Deposit Account No. 50-1349.

Applicant has not herein increased the number of claims beyond the amount for which "additional claims fees" have been previously paid. Therefore, the check enclosed herewith does not include any amount intended to cover any additional claims fees. If, however, the appropriate amount has not been specifically submitted in that check, please charge any additional fees or credit any overpayments to Deposit Account No. 50-1349.

If there are any other fees due in connection with the filing of this Response and Amendment or the RCE, please charge any necessary fees to Deposit Account No. 50-1349.

The Examiner is specifically invited to contact Applicants' undersigned attorneys by telephone to discuss the present claims if the Examiner would like to discuss additional claim language that would allow the present application to go toward immediate allowance.

Respectfully submitted,

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